

**SAFETY SHIELD FOR MEDICAL NEEDLES**

5 **CROSS-REFERENCE TO RELATED APPLICATIONS**

This patent application is a continuation-in-part of U.S. Utility Patent Application Serial No. 10/409,819, filed in the U.S. Patent and Trademark Office on April 8, 2003 by Ferguson et al., which claims priority to U.S. Utility Patent Application Serial No. 10/322,288, filed in the U.S. Patent and Trademark Office on December 17, 2002 by Ferguson et al., and U.S. Provisional Patent application Serial No. 60/424,655, filed in the U.S. Patent and Trademark Office on November 7, 2002 by Bagley et al., and U.S. Utility Patent Application Serial No. 10/202,201, filed in the U.S. Patent and Trademark Office on July 23, 2002 by Ferguson, which is a continuation-in-part of U.S. Utility Patent Application Serial No. 09/809,357, filed in the U.S. Patent and Trademark Office on March 15, 2001 by Ferguson et al., the entire contents of each of these disclosures being hereby incorporated by reference herein.

**BACKGROUND**

1. **Technical Field**

The present disclosure generally relates to safety shields for medical needles, and more particularly, to safety shields that protect a needle point of a medical needle.

20 2. **Description of the Related Art**

Problems associated with inadvertent needle sticks are well known in the art of blood sampling, percutaneous medication injection and other medical procedures involving use of medical needles. Significant attention has been focused on needle stick problems due to the contemporary sensitivity of exposure to AIDS, Hepatitis and other serious blood-borne pathogen exposures.

Procedures for removing a needle from a patient commonly require a technician to use one hand to place pressure at the wound site where the needle is being withdrawn, while removing the needle device with the other hand. It is also common practice for an attending technician to give higher priority to care for the wound than is given to disposal of a needle. In the case of typical needle devices without safety shields, such priority either requires the

convenience of an available sharps container within reach or another means for safe disposal without leaving the patient's side. Providing adequate care while following safety procedures is often compounded by the patient's physical condition and mental state, such as in burn units and psychiatric wards. Under such conditions, it is difficult to properly dispose of a used needle while caring for a patient.

The widespread knowledge and history associated with needle care and disposal problems have resulted in numerous devices for preventing accidental needle sticks. Problems of current safety devices include difficulty of use and high cost due to their complexity and number of parts.

Other known devices employ sheaths that are spring activated, telescoping, pivoting, etc. These devices, however, may disadvantageously misfire or be cumbersome to activate. Further drawbacks of current devices include high manufacturing cost due to complexity and the number of parts. Thus, these type prior art devices may not adequately and reliably shield medical needle apparatus to prevent hazardous exposure.

Consequently, there remains a need to provide a more satisfactory solution for needle safety devices by overcoming the disadvantages and drawbacks of the prior art. Therefore, it would be desirable to provide a more adequate and reliable medical needle shield apparatus which employs a safety shield slidably movable along a medical needle to prevent hazardous exposure to a needle tip. Such a needle shield apparatus should be easily and reliably movable to shield a needle tip of a needle cannula.

## **SUMMARY**

Accordingly, the present disclosure addresses a need for a medical needle shield apparatus which effectively and inexpensively protects a tip of a medical needle after use. The present disclosure resolves related disadvantages and drawbacks experienced in the art. More specifically, the apparatus and method of this invention constitute an important advance in the art of safety needle devices.

In one particular embodiment, a medical needle shield apparatus is provided in accordance with the principles of the present disclosure. The medical needle shield apparatus includes a shield that is extensible from a retracted position to an extended position to enclose a distal end of a needle. A binding member is disposed within the shield and defines binding

surfaces that form an aperture configured for slidable receipt of the needle between the retracted position and the extended position. The binding member includes one or more drag inducing members extending therefrom, such that the one or more drag inducing members engage the needle during slidable receipt of the needle to create a drag force with the needle. The drag force causes rotation of the binding member relative to a longitudinal axis of the needle such that the binding surfaces engage the needle to prevent slidable movement of the needle in the extended position of the shield. The binding member further includes a retainer extending therefrom such that the retainer is engageable with the needle to prevent rotation of the binding member. The shield further includes a hub retainer being configured to engage a catheter hub.

In another embodiment, the binding member includes separate frictional members that are disposed on a proximal side and a distal side of the binding member. The friction members allow sliding of the needle therewith and provide a frictional drag similar to the drag inducing members. The drag force causes rotation of the binding member relative to a longitudinal axis of the needle such that the binding surfaces engage the needle to prevent slidable movement of the needle in the extended position of the shield. Alternatively, the friction members may form a monolithic member that joins two members. The members engage the needle and binding member to prevent axial movement of the needle.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

The foregoing and other features and advantages of the present invention will be more fully understood from the following detailed description of the exemplary embodiments, taken in conjunction with the accompanying drawings in which:

FIGURE 1 is a perspective view of one particular embodiment of a medical needle shield apparatus in accordance with the principles of the present invention;

FIGURE 2 is a cross-sectional perspective view of the medical needle shield apparatus shown in FIGURE 1 with a housing section separated therefrom;

FIGURE 3 is an enlarged perspective cutaway view of the medical needle shield apparatus shown in FIGURE 2;

FIGURE 3A is an enlarged perspective view of an alternate embodiment of the medical needle shield apparatus shown in FIGURE 2;

FIGURE 3B is an enlarged perspective view of an alternate embodiment of the medical needle shield apparatus shown in FIGURE 2;

FIGURE 3C is an enlarged perspective view of an alternate embodiment of the medical needle shield apparatus shown in FIGURE 2;

5        FIGURE 4 is a perspective cutaway view of the medical needle shield apparatus shown in FIGURE 3;

FIGURE 5 is a cross-sectional perspective view of the medical needle shield apparatus shown in FIGURE 2 having a shield thereof extended;

10       FIGURE 6 is an enlarged perspective view of a binding member of the medical needle shield apparatus shown in FIGURE 2;

FIGURE 7 is an alternative cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 3;

FIGURE 8 is a perspective view of an inner surface of a housing section of the medical needle shield apparatus shown in FIGURE 3;

15       FIGURE 9 is a perspective cutaway view of the medical needle shield apparatus shown in FIGURE 3 with the shield in an extended position;

FIGURE 10 is a perspective view of the medical needle shield apparatus shown in FIGURE 1 with the shield in an extended position;

20       FIGURE 11 is an enlarged perspective view of an alternate binding member of the medical needle shield apparatus shown in FIGURE 6;

FIGURE 12 is an enlarged perspective view of another alternate binding member of the medical needle shield apparatus shown in FIGURE 3;

FIGURE 13 is an enlarged cross-sectional perspective cutaway view of an alternate embodiment of the medical needle shield apparatus shown in FIGURE 1;

25       FIGURE 14 is an enlarged cross-sectional perspective cutaway view of an alternate embodiment of the medical needle shield apparatus shown in FIGURE 1;

FIGURE 15 is an enlarged cross-sectional perspective cutaway view of another embodiment of the medical needle shield apparatus shown in FIGURE 1;

FIGURE 16 is an enlarged cross-sectional perspective cutaway view of another embodiment of the medical needle shield apparatus shown in FIGURE 1;

FIGURE 17 is a cross-sectional perspective view of another embodiment of the medical needle shield apparatus shown in FIGURE 1 with an outer rotatable housing separated therefrom;

FIGURE 18 is an enlarged cross-sectional perspective cutaway view of a distal end of the medical needle shield apparatus shown in FIGURE 17;

FIGURE 19 is an enlarged perspective view of the rotatable housing of the medical needle shield apparatus shown in FIGURE 17;

FIGURE 20 is an enlarged perspective view of a portion of the housing of the medical needle shield apparatus shown in FIGURE 17;

FIGURE 21 is a cross-sectional perspective view of another embodiment of the medical needle shield apparatus shown in FIGURE 17;

FIGURE 22 is a cross-sectional perspective view of the medical needle shield apparatus shown in FIGURE 21 with a catheter hub removed;

FIGURE 23 is an enlarged cross-sectional perspective view of another embodiment of the medical needle shield apparatus shown in FIGURE 1 with a hub support member separated;

FIGURE 24 is a cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 23 with the catheter hub removed;

FIGURE 25 is a cross-sectional perspective cutaway view of another embodiment of the medical needle shield apparatus shown in FIGURE 1 with a rotatable housing separated;

FIGURE 26 is a cross-sectional perspective view of another embodiment of the medical needle shield apparatus shown in FIGURE 1;

FIGURE 27 is a perspective cutaway view of the medical needle shield apparatus shown in FIGURE 26 with the shield in an extended position;

FIGURE 28 is an enlarged perspective view of the binding member of the medical needle shield apparatus shown in FIGURE 26;

FIGURE 29 is an enlarged perspective view of the bearing of the medical needle shield apparatus shown in FIGURE 26;

FIGURE 30 is a cross-sectional perspective cutaway view of another embodiment of the medical needle shield apparatus shown in FIGURE 1;

5        FIGURE 31 is a cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 30;

FIGURE 32 is a cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 30;

10       FIGURE 33 is a cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 30;

FIGURE 34 is a cross-sectional perspective view of another embodiment of the medical needle shield apparatus shown in FIGURE 1 with a housing section separated therefrom;

FIGURE 35 is a cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 34;

15       FIGURE 36 is a cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 34;

FIGURE 37 is a cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 34;

20       FIGURE 38 is a cross-sectional perspective view of another embodiment of the medical needle shield apparatus shown in FIGURE 1;

FIGURE 39 is a cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 38 in the extended position;

FIGURE 40 is a cross-sectional perspective view of another embodiment of the medical needle shield apparatus shown in FIGURE 1;

25       FIGURE 41 is a cross-sectional perspective cutaway view of the medical needle shield apparatus shown in FIGURE 40 in the extended position;

FIGURE 42 is a cross-sectional perspective view of another embodiment of the medical needle shield apparatus shown in FIGURE 1;

FIGURE 43 is a cross-sectional view of the medical needle shield apparatus shown in FIGURE 42;

FIGURE 44 is a cross-sectional perspective view of the medical needle shield apparatus shown in FIGURE 42 in the extended position;

5        FIGURE 45 is a cross-sectional view of the medical needle shield apparatus shown in FIGURE 44;

FIGURE 46 is a cross-sectional view of the medical needle shield apparatus shown in FIGURE 44;

10       FIGURE 47 is a cross-sectional perspective view of another embodiment of the medical needle shield apparatus shown in FIGURE 1;

FIGURE 48 is a cross-sectional view of the medical needle shield apparatus shown in FIGURE 47;

FIGURE 49 is an enlarged perspective view of the binding member of the medical needle shield apparatus shown in FIGURE 47;

15       FIGURE 50 is an enlarged perspective view of the unitary friction member of the medical needle shield apparatus shown in FIGURE 47;

FIGURE 51 is a cross-sectional perspective view of the medical needle shield apparatus shown in FIGURE 47 in the extended position; and

20       FIGURE 52 is an enlarged perspective view of another embodiment of the binding member of the medical needle shield apparatus shown in FIGURE 47.

#### **DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS**

25       The exemplary embodiments of the medical needle shield apparatus and methods of operation disclosed are discussed in terms of medical needles for infusion of intravenous fluids, medication infusion or fluid collection, and more particularly, in terms of needle shield apparatus employed with a needle cannula that prevent hazardous exposure to a needle tip, including, for example, inadvertent needle sticks. It is contemplated that the medical needle safety shield apparatus may be utilized for medical needle applications including, but not limited to, fluid infusion, fluid collection, catheters, catheter introducers, guidewire introducers, spinal and epidural, biopsy, aphaeresis, dialysis, blood donor, Veress needles, Huber needles, winged

(“butterfly”) needles, etc. It is envisioned that the present disclosure, however, finds application to a wide variety of cannula needles and devices for the infusion of preventive medications, medicaments, therapeutics, etc. to a subject. It is also envisioned that the present disclosure may be employed for collection of body fluids including those employed during procedures relating to phlebotomy, digestive, intestinal, urinary, veterinary, etc.

In the discussion that follows, the term “proximal” refers to a portion of a structure that is closer to a clinician, and the term “distal” refers to a portion that is further from the clinician. As used herein, the term “subject” refers to a patient that receives infusions or has blood and/or fluid collected therefrom using the medical needle shield apparatus. According to the present disclosure, the term “clinician” refers to an individual administering an infusion, performing fluid collection, installing or removing a needle cannula from a medical needle shield apparatus and may include support personnel.

The following discussion includes a description of the medical needle shield apparatus, followed by a description of the method of operating the medical needle shield apparatus in accordance with the present disclosure. Reference will now be made in detail to the exemplary embodiments of the disclosure, which are illustrated in the accompanying figures.

Turning now to the figures, like components are designated by like reference numerals throughout the several views. Referring initially to FIGURES 1-10, there is illustrated a medical needle shield apparatus, constructed in accordance with the principals of the present disclosure. The medical needle shield apparatus includes a shield 1 being extensible from a retracted position (FIGURE 1) to an extended position (FIGURE 10) to enclose a distal end of a needle 6. A binding member 5 is disposed within shield 1 and defines binding surfaces 22. Binding surfaces 22 form an aperture 21 that is configured for receipt of needle 6.

Binding member 5 includes one or more drag inducing members, such as, for example, friction members 26 that extend therefrom. Friction members 26 engage needle 6 to facilitate rotation, as will be discussed, of binding member 5 relative to a longitudinal axis  $x$  of needle 6. Binding member 5 also includes a retainer 14 extending therefrom. Retainer 14 has a first portion, such as, for example, a needle communicating surface 23 that engages needle 6 to prevent rotation of binding member 5 prior to the extended position.

Retainer 14 also has a second portion, such as, for example, a hub retainer 14A. A catheter hub 4 is disposed about needle 6. Catheter hub 4 is releasably mounted with shield 1 via



releasable engagement with hub retainer 14A. The medical needle shield apparatus is advantageously configured to prevent hazardous exposure to distal end 15 of needle cannula 6, as will be discussed below.

5 The components of the medical needle shield apparatus can be fabricated from a material suitable for medical applications, such as, for example, polymeric or metals, such as stainless steel, depending on the particular medical application and/or preference of a clinician. Semi-rigid and rigid polymeric are contemplated for fabrication, as well as resilient materials, such as molded medical grade polypropylene. However, one skilled in the art will realize that other materials and fabrication methods suitable for assembly and manufacture, in accordance with the  
10 present disclosure, also would be appropriate.

A catheter 3 includes catheter hub 4, which forms part of a catheter 3 and introducer assembly that may be employed with the medical needle shield apparatus. Shield 1 and catheter 3 slidably support needle 6 for use thereof. A handle 13 is mounted with needle 6 to facilitate manipulation thereof. The term catheter may also be used to describe the outer needle, sleeve, or  
15 tube of a medical needle assembly. The term needle may also be used to describe the inner needle, wire, or stylet, which is generally metallic, but may be made of any suitable material including polymers.

Catheter hub 4 has a hub slot 24 for receipt and engagement with hub retainer 14A. Catheter hub 4 has a finger tab 5A for urging catheter 3 toward distal end 15 of needle 6,  
20 facilitating removal of catheter 3 from shield 1, and use during a catheter application. It is contemplated that finger tab 5A may be alternatively configured and dimensioned according to the needle application or disposed on shield 1.

Shield 1 includes a housing 2 for disposition of binding member 5. Shield 1 includes housing first section 8 and housing second section 9, as shown in FIGURE 2. It is envisioned  
25 that housing sections 8, 9 may be variously configured and dimensioned such as, for example, rectangular, spherical, etc. It is further envisioned that housing sections 8, 9 may be joined by any appropriate process such as, for example, snap fit, adhesive, solvent weld, thermal weld, ultrasonic weld, screw, rivet, etc. Alternatively, housing 2 may be monolithically formed or integrally assembled of multiple sections and may be substantially transparent, opaque, etc.  
30 Housing sections 8, 9 may include ribs, ridges, etc. to facilitate manipulation of the medical needle shield apparatus.

Referring to FIGURE 3, a flange 4A of catheter hub 4 is concentrically supported by a control surface 10 disposed about an inner surface of housing 2. Control surface 10 engages an outer surface 11 of flange 4A for guiding and supporting the extension of catheter hub 4 therefrom. It is contemplated that control surface 10 may engage other portions of catheter hub 4.

5       Housing 2 may include hub stop surfaces 12 that facilitate positioning of catheter hub 4 with housing 2. Hub stop surfaces 12 prevent proximal movement of catheter hub 4 during mounting with and relative to housing 2. Hub stop surfaces 12 advantageously facilitates control of the degree of insertion with housing 2 according to the requirements of a particular catheter application. One or a plurality of hub stop surfaces 12 may be employed. It is contemplated that  
10   hub stop surfaces 12 may include springs, clips, etc. to facilitate attachment with catheter hub 4.

Referring to FIGURES 4-9, binding member 5 is monolithically formed and includes an aperture plate 18, frictional members 26, and retainer 14, which includes end sensing member 19, needle communicating surface 23 and hub retainer 14A. Aperture plate 18 has a rectangular, generally planar configuration with sufficient stiffness to produce forces for binding needle 6, as  
15   will be discussed. It is envisioned that aperture plate 18 may have an arcuate surface, undulating, etc. It is further envisioned that aperture plate 18 may have various degrees of stiffness according to the requirements of a particular application.

Frictional members 26 may be monolithically formed with binding member 5 and extend from aperture plate 18 in association therewith for alignment with aperture 21 and engagement  
20   with needle 6. Each frictional member 26 includes a flexible arm 26A, which are spaced apart to facilitate sliding engagement with needle 6. Such engagement creates a frictional drag force with needle 6. This frictional drag force causes binding member 5 to move with needle 6, which generates a canting force in retainer 14 and inclination of aperture plate 18, discussed below. The canting force and inclination urge rotation of binding member 5. It is contemplated that a  
25   single friction member may be employed.

As facilitated by movement of needle 6, the canting force causes a lever or moment of retainer 14, which is opposed to prevent rotation of binding member 5. The canting force is opposed by engagement of needle communicating surface 23 with needle 6 in a non-binding or sliding orientation of binding member 5.

30       End sensing member 19 extends distally from aperture plate 18. End sensing member 19 may be perpendicularly oriented relative to a plane defined by aperture plate 18. This

perpendicular orientation facilitates inclination of aperture plate 18 for disposal in a binding or non-binding orientation of binding member 5. It is envisioned that end sensing member 19 may be variously oriented with aperture plate 18 and may flexibly extend therefrom.

Needle communicating surface 23 extends from end sensing member 19 in a substantially perpendicular orientation to aperture plate 18 and in alignment with needle 6. In a non-binding or sliding orientation, needle communicating surface 23 extends in substantially parallel alignment with needle 6 for slidable engagement therewith, as shown in FIGURE 5. Needle communicating surface 23 engages needle 6 and maintains the non-binding or sliding orientation of aperture plate 18 by opposing the canting force of end sensing member 19 directed to needle 6. The canting force, as created by the drag force described below, is generated by friction members 26 engaging aperture plate 18, and in cooperation with blocking member 16, causing aperture plate 18 to move to a binding position. Inclination, however, is prevented in the non-binding or sliding orientation because of the engagement of needle communicating surface 23 with needle 6, as shown in FIGURE 5. As needle 6 is retracted proximally and shield is extended distally, needle 6 continues to slideably engage needle communicating surface 23, as shown in FIGURE 5.

A drag force is created between friction members 26 and needle 6. The drag force in conjunction with blocking member 16, cause aperture plate 18 to move to the binding position. Note that the force created by blocking member 16 acts in a direction opposite of the drag force. This causes a force couple which moves the aperture plate 18 to the binding position. As needle 6 is released from engagement with needle communicating surface 23, aperture plate 18 and retainer 14 move to the binding position. Rotation is no longer opposed by engagement with needle 6 at needle communicating surface 23. Thus, aperture plate 18, attached to retainer 14, is subject to inclination into a binding orientation. Rotation of aperture plate 18 causes binding surfaces 22 to frictionally engage needle 6 to prevent movement thereof. Blocking members 16, 17 cause aperture plate 18 to move to the binding position as forces are imposed on shield 1 in either direction along longitudinal axis  $x$ . This maintains needle 6 within shield 1 to avoid hazardous exposure to distal end 15. It is envisioned that needle communicating surface 23 may include ribs, projections, cavities, etc. for engagement with needle 6 or that a portion of needle communicating surface 23 engages needle 6.

It is also envisioned that binding member 5 may be configured such that aperture 21 does not engage needle 6 until binding occurs. In this embodiment, blocking members 16 and 17 are configured to initiate rotation of binding member 5 upon which the rotation of aperture plate 18 causes binding surfaces 22 to frictionally engage needle 6 to prevent movement thereof.

5           Hub retainer 14A extends transversely from a distal end of needle communicating surface 23. Hub retainer 14A extends a sufficient length for corresponding receipt within a hub slot 24 of catheter hub 4, as shown in FIGURE 5. In association with a non-binding or sliding orientation of binding member 5, hub retainer 14A engages catheter hub 4, in hub slot 24, for releasably mounting with housing 2 of shield 1.

10           As needle 6 is retracted in a proximal direction and shield 1 is extended in a distal direction, as shown in FIGURE 7, retainer 14 rotates direction relative to longitudinal axis  $x$  due to the canting forces generated by friction members 26. Hub retainer 14A disengages from hub slot 24 to release catheter hub 4 from housing 2. A clinician may manipulate finger tab 5A to manipulate catheter 3 distally and apart from shield 1. It is contemplated that hub retainer 14A  
15           may be variously oriented from needle communicating surface 23. It is further contemplated that hub slot 24 may be variously dimensioned and disposed on the circumference of catheter hub 4. Hub slot 24 may include tabs, etc. for retention with hub retainer 14A.

Aperture 21 is formed within aperture plate 18 for slideable engagement with needle 6 during movement between the retracted position and the extended position of shield 1. Aperture  
20           21 includes binding surfaces 22 formed on opposing sides of aperture 21 that engage needle 6 to prevent movement thereof in the extended position of shield 1. It is contemplated that engagement to prevent movement of needle 6 may include penetrating, frictional, interference, etc. It is envisioned that aperture 21 may have various geometric configurations, such as radial, polygonal, etc. It is further envisioned that aperture 21 may define an open cavity within  
25           aperture plate 18, such as, for example, "U" shaped and open to one or a plurality of edges of aperture plate 18.

The inclination of aperture plate 18 relative to longitudinal axis  $x$  facilitates sliding and binding, via binding surfaces 22 of aperture 21, of needle 6 within shield 1 to prevent hazardous exposure to distal end 15. For example, as shown in FIGURE 4, aperture plate 18 is oriented at  
30           an angle of approximately  $90^\circ$  relative to longitudinal axis  $x$  such that aperture plate 18 is disposed substantially perpendicular to needle 6. In this non-binding or sliding orientation,

needle 6 is free to slide within aperture 21. Referring to FIGURE 5, as needle 6 is retracted and shield 1 is extended, needle 6 continues to engage needle communicating surface 23 and aperture plate 18 maintains its perpendicular orientation relative to longitudinal axis  $x$ .

Referring to FIGURES 7 and 9, shield 1 is manipulated such that friction members 26 cause binding member 5 to rotate relative to longitudinal axis  $x$ . Aperture plate 18 rotates out of perpendicular alignment with needle 6 such that aperture plate is oriented at an angle  $\alpha$ , which is less than  $90^\circ$  with respect to longitudinal axis  $x$ . It is contemplated that angle  $\alpha$  may be measured from either side of aperture plate 18.

Aperture plate 18 rotates to angle  $\alpha$  and binding member 5 approaches a binding orientation. The binding orientation includes engagement of binding surfaces 22 with needle 6 due to the binding orientation of aperture plate 18. This engagement creates binding frictional forces on needle 6, to prevent movement of needle 6 relative to shield 1 and to maintain distal end 15 within shield 1 to prevent hazardous exposure thereto.

Inclination of binding member 5 is also affected by blocking members 16, 17 of housing 2. Blocking members 16, 17 are formed with housing section 8 and are disposed not to interfere with needle 6. Blocking members 16, 17 define surfaces 16A, 17A respectively, that facilitate disposal of aperture plate 18 in a binding orientation.

For example, as shown in FIGURE 2, shield 1 is in a retracted position and needle 6 is fully extended. Binding member 5 and aperture plate 18 are in a non-binding or sliding orientation such that aperture plate 18 is substantially perpendicular to longitudinal axis  $x$ . Blocking members 16, 17 may engage aperture plate 18 to maintain aperture plate 18 in the perpendicular orientation. Blocking members 16, 17 may also maintain such orientation during extension of needle 6 or may not engage needle 6.

As needle 6 is retracted and shield 1 is extended, friction members 26 create a drag force via engagement with needle 6 on binding member 5, as shown in FIGURE 7, causing aperture plate 18 to rotate to the binding orientation. Blocking member surfaces 16A, 17A engage aperture plate 18 to facilitate rotation thereof from the perpendicular orientation into the binding orientation such that binding surfaces 22 engage needle 6. This configuration prevents movement of needle 6.

Binding of binding member 5 to needle 6 is facilitated by the friction or binding force generated between binding surfaces 22 and needle 6. This frictional engagement prevents axial movement of needle 6 relative to housing 2 when shield 1 is in the extended position. This configuration advantageously prevents hazardous exposure to needle 6. It is contemplated that binding surfaces 22 may include sharp edges to increase frictional engagement. It is further contemplated that the friction or binding force may be varied by altering factors, such as, for example, aperture 21 dimension, needle 6 diameter, aperture plate 18 thickness, the dimension from blocking members 16, 17 contact point to the centerline of needle 6 and the coefficient of friction between aperture 21 and needle 6 for any force applied to housing 2 up to the point of material failure, etc., depending on the particular requirements of a needle application.

Referring to FIGURE 3A, another alternate embodiment of binding member 5' is shown (similar to binding member 5 shown in FIGURE 6, but without frictional members 26). Binding member 5' includes a drag inducing member, such as, aperture 21 that is formed by binding surfaces 22 (see FIGURE 6). Aperture 21 facilitates sliding engagement with needle cannula 6. Such engagement creates a frictional drag force with needle cannula 6. This frictional drag force causes binding member 5' to move with needle cannula 6. In a non-binding or sliding orientation of binding member 5', aperture plate 18' engages blocking members 16, 17 causing a canting force in end sensing member 19, as discussed.

Referring to FIGURES 3B and 3C, alternate embodiments of binding member 5' are shown. FIGURE 3B shows a member 44 having an aperture 45, with member 44 being disposed on aperture plate 18'. The diameter of aperture 45 is smaller than the diameter of aperture 21. Binding member 5' includes a drag inducing member, such as, aperture 45 that is formed by binding surfaces 46. Aperture 45 facilitates sliding engagement with needle cannula 6. Such engagement creates a frictional drag force with needle cannula 6, and in cooperation with blocking member 16, cause aperture plate 18' to move to the binding position. FIGURE 3C shows a member 41 having elements 42 defining an opening 40, with member 41 being disposed on aperture plate 18'. Binding member 5' includes a drag inducing member, such as, opening 40 that is formed by surfaces 43. The distance between surfaces 43 is smaller than the diameter of aperture 21. Surfaces 43 facilitate sliding engagement with needle cannula 6. Such engagement creates a frictional drag force with needle cannula 6, and in cooperation with blocking member 16, cause aperture plate 18' to move to the binding position. It is contemplated that members 41 and 44 may be fabricated from materials such as polymeric, metals, elastomeric materials, etc.

Referring to FIGURES 11 and 12, alternate embodiments of binding member 5 are shown. Aperture plate 18 has a polygonal geometric configuration and end sensing member 19 has member arms 19A that extend in a uniform axial orientation, parallel to needle 6. Needle communicating surface 23 extends transversely to bridge a cavity 23A between arms 19A.

5 Binding member 5 includes hub retainers 14A for engagement with hub slot 24, similar to that described. Friction members 26 extend laterally from aperture plate 18. Friction member arms 26A may include a planar engagement surface, as shown in FIGURE 11, or alternatively, may include a curled engagement surface, as shown in FIGURE 12, for engagement with needle 6.

10 In operation, the medical needle shield apparatus, similar to that described in accordance with the principles of the present disclosure is provided for employment with catheter 3. The components of the medical needle shield apparatus are fabricated, properly sterilized and otherwise prepared for storage, shipment and use.

Referring to FIGURES 1 and 2, the clinician (not shown) manipulates handle 13 such that shield 1 is in the retracted position and binding member 5 is in a non-binding or sliding  
15 orientation. Needle 6 is fully extended relative to shield 1 such that catheter 3 is disposed about needle 6 and catheter hub 4 is releasably mounted with housing 2. A procedure employing the medical needle shield apparatus with catheter 3 is performed by the clinician to completion.

Needle 6 is retracted proximally such that shield 1 is extended toward the extended position, as shown in FIGURE 5. Binding member 5 is in the non-binding or sliding orientation  
20 such needle 6 engages needle communicating surface 23 and binding surfaces 22 facilitate sliding through aperture 21, as discussed.

Referring to FIGURES 7, 9 and 10, as needle 6 clears needle communicating surface 23, retainer 14 is free to rotate due to the canting forces created via the engagement of needle 6 with frictional members 26. Aperture plate 18 rotates relative to longitudinal axis  $x$ , from the perpendicular orientation to an inclination for a binding orientation as facilitated by blocking  
25 members 16, 17, as shown in FIGURE 9. Aperture plate 18 rotates to angle  $\alpha$  relative to longitudinal axis  $x$ .

Hub retainer 14A disengages from hub slot 24 such that catheter hub 4 is released from housing 2. Catheter 3 can be manipulated distally via finger tab 5A. In the binding orientation,  
30 binding surfaces 22 engage needle 6 to bind and prevent axial movement of needle 6 within

housing 2. Shield 1 is disposed in the extended position to prevent hazardous exposure to distal end 15, as shown in FIGURE 10.

In an alternate embodiment, as shown in FIGURE 13, binding member 5 includes separate frictional members 26' that are disposed on a proximal side and a distal side of aperture plate 18, respectively. Friction members 26' are friction fit polymer O-rings, which allow sliding of needle 6 therewith and provide a frictional drag force, similar to that discussed, via engagement with needle 6. The drag force is created as needle 6 slides and friction members 26' engage aperture plate 18. Friction members 26' engage aperture plate 18, and in cooperation with blocking member 16, cause aperture plate 18 to move to the binding position. Binding surfaces 22 engage needle 6 to prevent axial movement of needle 6, as discussed. It is contemplated that friction members 26' may be fabricated from materials such as polymeric, metals, etc.

Alternatively, friction members 26' may form a monolithic member that links or joins two members 26", as shown in FIGURE 14. Members 26" engage needle 6 and aperture plate 18 to prevent axial movement of needle 6, similar to that discussed with regard to FIGURE 13. It is envisioned that aperture 21 may create a drag force via engagement with needle 6 to cause rotation of binding member 5, similar to that described. It is further envisioned that materials such as, for example, jells, greases, etc. may be employed to create a frictional drag force with needle 6 to cause rotation of binding member 5.

In an alternate embodiment, as shown in FIGURE 15, housing 2 includes hub support 20. Hub support 20 is received by catheter hub 4 to advantageously facilitate removable mounting of catheter hub 4 with shield 1. Alternatively, as shown in FIGURE 16, control surface 10 of housing 2 may be cut back or eliminated. This configuration allows hub support 20 to solely facilitate mounting of catheter hub 4 via a concentric relationship therewith.

Referring to FIGURES 17-20, another alternate embodiment of the medical needle safety apparatus is shown. A rotatable housing 25, having sections 29, is disposed for rotation and enclosure of shield 1. Rotatable housing 25 is mounted within handle 13 and freely rotates relative to shield 1 and needle 6 in the extended position of shield 1. Relative rotation of rotatable housing 25 is facilitated by support at opening 27 and support 30 formed in rotatable housing 25. Axles 31, 31A are rotationally supported in openings 30, 27, respectively. In a binding orientation, the bearing configuration supports rotation of rotatable housing 25 relative



to shield 1 and needle 6. Bearing 40 includes blocking member 16, 17, similar to those discussed. Needle 6 passes through blocking members 16, 17 for slidable movement relative thereto. The halves of axle 31 are spaced apart such that needle 6 and retainer 14 may be disposed therein.

5 This configuration prevents rotation of shield 1 about longitudinal axis  $x$  of needle 6 such that binding member 5 is not undesirably rotated to disturb the protective binding engagement with needle 6. Thus, the possibility of intentionally abusing and defeating the protective configuration of shield 1, in the extended position, by manually and abusively twisting shield 1 is reduced. It is envisioned that, the length of opening 27 may be increased such that the radial  
10 clearance of opening 27 with needle 6 limits tilting of shield 1 within rotatable housing 25. This configuration prevents radial contact of shield 1 with rotatable housing 25 and allows elimination of a front bearing.

Referring to FIGURES 21 and 22, in an alternate embodiment, bearing 40 includes a thrust collar 32 mounted to needle 6. A corresponding thrust base 33 of rotatable housing 25 is  
15 configured to support thrust collar 32 and controls relative axial movement between bearing 40 and rotatable housing 25. Thrust collar 32 freely rotates within thrust base 33 to facilitate rotation of needle 6 and limit tilting of shield 1 within rotatable housing 25. Alternatively, as shown FIGURES 23 and 24, rotatable housing 25 includes a hub support 20, similar to that discussed with regard to FIGURE 15. In another alternative, as shown in FIGURE 25, control  
20 surface 10 of bearing 40 may be cut back or eliminated, similar to that discussed with regard to FIGURE 16.

Referring to FIGURES 26-29, another alternate embodiment of the medical needle safety apparatus is shown. A rotatable housing 25 is disposed for rotation and enclosure of shield 1. Rotatable housing 25 freely rotates relative to shield 1 and needle 6 in the extended position of  
25 shield 1. Relative rotation of rotatable housing 25 is facilitated by support at opening 27 formed in rotatable housing 25. Axles 31, 31A are rotationally supported in opening 27. In a binding orientation, the bearing configuration supports rotation of rotatable housing 25 relative to shield 1 and needle 6. Bearing 40 includes blocking member 16, 17, similar to those discussed. Needle 6 passes through blocking members 16, 17 for slidable movement relative thereto. The halves of  
30 axle 31 are spaced apart such that needle 6 and retainer 14 may be disposed therein.

This configuration prevents rotation of shield 1 about longitudinal axis  $x$  of needle 6 such that binding member 5 is not undesirably rotated to disturb the protective binding engagement with needle 6. Thus, the possibility of intentionally abusing and defeating the protective configuration of shield 1, in the extended position, by manually and abusively twisting shield 1 is reduced. It is envisioned that, the length of opening 27 may be increased such that the radial clearance of opening 27 with needle 6 limits tilting of shield 1 within rotatable housing 25. This configuration prevents radial contact of shield 1 with rotatable housing 25 and allows elimination of a front bearing.

Referring to FIGURES 30-33, hub retainer 14A may be hingedly connected to bearing 40, such as by a living hinge or the like. FIGURES 30 and 31 illustrate shield 1 prior to activation, wherein Hub retainer 14A includes a portion 34 for engagement with retainer 14 for maintaining hub retainer 14A in hub slot 24. FIGURES 32 and 33 illustrate shield 1 after activation, wherein the movement of retainer 14 upon activation of shield 1 in the extended position allows portion 34 to move and release hub retainer 14A from hub slot 24.

The embodiments illustrated in FIGURES 34-37 depict a hub retainer 14A hingedly connected to housing 2. FIGURES 34 and 35 illustrate shield 1 prior to activation, wherein Hub retainer 14A includes a portion 34 for engagement with retainer 14 for maintaining hub retainer 14A in hub slot 24. FIGURES 36 and 37 illustrate shield 1 after activation, wherein the movement of retainer 14 upon activation of shield 1 in the extended position allows portion 34 to move and release hub retainer 14A from hub slot 24.

The embodiments illustrated in FIGURES 38-39 depict a shield having a hub retainer 14A which engages the catheter hub 4 via flange 42. FIGURE 38 illustrates shield 1 prior to activation. FIGURE 39 illustrates shield 1 after activation, wherein the movement of retainer 14 upon activation of shield 1 in the extended position allows retainer 14 to move and release hub retainer 14A from flange 42. Retainer shield 44 protects hub retainer 14A from being inadvertently moved from its intended position.

Referring to FIGURES 40-41, the illustrated embodiments depict a rotatable shield having a hub retainer 14A which engages the catheter hub 4 via flange 42. FIGURE 40 illustrates shield 1 prior to activation. FIGURE 41 illustrates shield 1 after activation, wherein the movement of retainer 14 upon activation of shield 1 in the extended position allows retainer 14 to move and release hub retainer 14A from flange 42. Retainer shield 44 extends

circumferentially to provide for rotation of hub retainer 14A about needle 6 and to protect hub retainer 14A from being inadvertently moved from its intended position.

Referring to FIGURES 42-46, another alternate embodiment of the medical needle safety apparatus is shown. FIGURES 42 and 43 illustrate shield 1 prior to activation, wherein binding member 46 is disposed within a cavity 54 of sliding member 48. Sliding member 48 receives needle 6 for slidable receipt via friction between the retracted position and extended position of shield 1. End sensing member 19 extends distally from sliding member 48. It is envisioned that end sensing member 19 may be variously oriented with sliding member 48 and may flexibly extend therefrom, such as by a hinge 52 or the like. Needle communicating surface 23 extends from end sensing member 19. In a non-binding or sliding orientation, needle communicating surface 23 slidably engages needle 6, as shown in FIGURES 42 and 43. Needle communicating surface 23 engages needle 6 and maintains the non-binding or sliding orientation of binding member 46 by opposing the force of end sensing member 19 directed to needle 6. The force, as created by the binding member against end sensing member 19 described below, is generated by ramp surface 50 engaging binding member 46. Binding engagement, however, is prevented in the non-binding or sliding orientation because of the engagement of needle communicating surface 23 with needle 6, as shown in FIGURES 42 and 43. As needle 6 is retracted proximally and shield is extended distally, needle 6 continues to slideably engage needle communicating surface 23, as shown in FIGURES 42 and 43. It is envisioned that needle communicating surface 23 may include ribs, projections, cavities, etc. for engagement with needle 6 or that a portion of needle communicating surface 23 engages needle 6.

Referring to FIGURES 44-46, as needle 6 is released from engagement with needle communicating surface 23 when the shield 1 is in the extended position, the force created by ramp 50 against binding member 46 causes end sensing member 19 to move and allow binding member 46 to contact needle 6 in binding engagement via binding surface on binding member 46. As shown in FIGURES 45 and 46, ramp surfaces 50 allow binding engagement of binding member 46 to needle 6 as the shield is moved in either axial direction along needle 6.

Catheter hub 4 has a hub slot 24 for receipt and engagement with hub retainer 14A. Hub retainer 14A extends from end sensing member 19. Hence, as needle 6 is released from engagement with needle communicating surface 23 disposed on end sensing member 19, hub retainer 14A is disengaged from catheter hub 4 for release therefrom.

Referring to FIGURES 47-52, another alternate embodiment of the medical needle safety apparatus is shown. The illustrated embodiments depict a rotatable shield wherein the binding member 5 rotates about bearing surfaces provided in cavity 56. FIGURES 47 and 48 illustrate shield 1 prior to activation. Retainer 14 extends from end sensing member 19, wherein retainer 14 supports the needle on opposing sides and maintains binding member 5 in a non-binding position prior to the shield being in the extended position. Binding member 5 is disposed in friction member 26" that forms a monolithic member for receiving needle 6 for slidable receipt via friction between the retracted position and extended position of shield 1, as shown in FIGURE 50. As needle 6 is retracted and shield 1 is extended, friction member 26" creates a drag force via engagement with needle 6 on binding member 5, as shown in FIGURES 47 and 48, causing binding member 5 to rotate to the binding orientation. Blocking member surfaces 16 and 17 engage binding member 5 to facilitate rotation thereof from the perpendicular orientation into the binding orientation such that binding surfaces 22 engage needle 6. This configuration prevents movement of needle 6. FIGURE 51 illustrates shield 1 after activation, wherein the movement of retainer 14 upon activation of shield 1 in the extended position allows retainer 14 to move and release hub retainer 14A from slot 24.

FIGURE 52 illustrates another embodiment of the binding member 5 having friction arms 26 to facilitate rotation of the binding member. It is envisioned that the embodiments including binding member 5 illustrated in FIGURE 25 may have blocking members incorporated into the housing as discussed in previously disclosed embodiments.

The invention of the present disclosure may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.